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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	**PAPER NUMBER**
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,488	MJALLI ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *47-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/30/2004, 9/13/2005 & 3/17/2006.

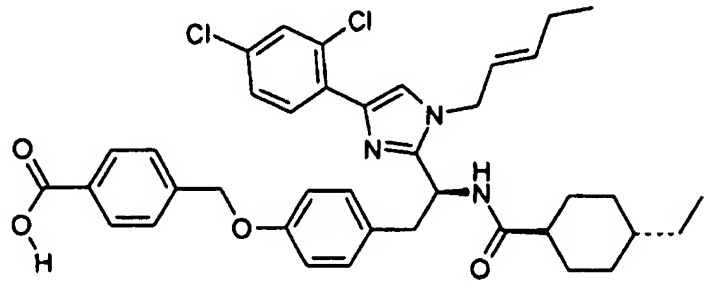
DETAILED ACTION

Claims 1-63 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III (claims 1-46), and the species of Example 319 found on page 287 of the instant specification (reproduced below), in the reply filed on October 27, 2006 is acknowledged.

Example 146



4-(4-{2-[4-(2,4-Dichloro-phenyl)-(E)-1-pent-2-enyl-1H-imidazol-2-yl]- (2S)-2-[(trans-4-ethyl-cyclohexanecarbonyl)-amino]-ethyl}-phenoxymethyl)-benzoic acid

The traversal is on the ground(s) that there would not be a serious burden on the Examiner if restriction were not required because a search of the prior art relevant to the claims of Group III would provide the relevant prior art for Groups I, II, IV, V and VI.

This is not found persuasive because separate search considerations are involved for each of the groups outlined in the Restriction Requirement. Further, a search of the products of Group III would not necessarily reveal references relevant to the inventions of Groups I, II, IV, V and VI. Note the prior art cited below. Also, the examination is also burdensome because of the 19 page IDS filed by Applicant on November 30, 2004 in addition to the 3 page IDS filed March 17, 2006 and the 1 page IDS filed September 13, 2005. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application were unrestricted.

Additionally, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant's compound genus of Claim 1 has a number of variables, including a multitude of definitions, and their permutations and combinations result in a vast number of compounds that are generically claimed. In

an attempt to examine the full scope of elected Group III, almost 19,000 CA Registry numbers were recovered on one database search alone. Additionally, and as stated above, the examination is also arduous because of the 19 page IDS filed by Applicant on November 30, 2004 in addition to the 3 page IDS filed March 17, 2006 and the 1 page IDS filed September 13, 2005. Therefore, the instant application will be examined according to MPEP 803.02.

The claims within elected Group III and the Information Disclosure Statements have been examined to the extent that they are readable on the elected species of Example 319. Since no prior art was found on the elected species, the examination was expanded within elected Group III until art was found, in which case, the examination stopped and art has been applied against the claims. Note, M.P.E.P. § 803.02. The

subject matter of the expanded search (inclusive of the elected species of Example 319) is as follows:

W is $N(R_2)$;

$\mathbf{Ar_1}$ is an optionally substituted phenyl;

$\mathbf{Ar_2}$ is an optionally substituted phenyl;

T is an optionally substituted phenyl;

$\mathbf{L_2}$ is a direct bond; and

all other variables are as defined.

The claims that are embraced by the subject matter of the expanded search are claims 1-46.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by the above indicated expanded search and Claims 47-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely

traversed the restriction (election) requirement in the reply filed on October 27, 2006.

Information Disclosure Statement

The Examiner has considered the 19 page IDS filed on November 30, 2004, the 3 page IDS filed March 17, 2006 and the 1 page IDS filed September 13, 2005.

Claim Objections

Claim 44 is objected to because of the following informalities: in claim 44, "pharmaceutical" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 34-37, 39 and 41-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

Applicant is claiming compositions for treating numerous diseases and disorders by administering a compound of formula (I). See, for example, instant claim 39. Additionally, claim 31 lists additional therapeutic agents but some of these agents are not adequately described in the instant specification (i.e., DPP-IV inhibitors, GLP-1 mimetics, insulin mimetics, fibrates, etc.). From the reading of the specification, it appears that Applicants are asserting that the embraced compounds, because of their mode action which involves the inhibition of protein

tyrosine phosphatases (PTPases), would be useful for treating numerous diseases and disorders such as cancer, AIDS, autoimmune diseases, infectious diseases, etc. The instant specification teaches that "treating" embraces prophylaxis of or preventing the onset of a disease or disorder (page 323-324).

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that cancer therapy, for example, remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, Vol. 286, October 15, 1999, pages 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, to maximize efficacy and minimize toxicity. Cancer classification has been based primarily on morphological appearance of

the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al., Science, Vol. 286, October 15, 1999, pages 531-537). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Additionally, inflammation is a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people

who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can be used to treat or prevent the onset of all of the diseases embraced by the claims is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating or preventing the onset of any or all conditions by administering the instant claimed compounds.

The breadth of the claims

The breadth of the claims is treating or preventing the onset of all of the diseases and disorders generically embraced in the claim language.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological

activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-46 are provisionally rejected on the ground of nonstatutory obviousness-type double

patenting as being unpatentable over claims 1-16, 19-26, 28-52 and 70 of copending Application No. 11/056,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in copending Application No. 11/056,498. See, for example, the first species in claim 32 in copending Application No. 11/056,498.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating obesity).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, obesity. The instant

claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11, 13-17, 22, 24 and 26-46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by:

a) Robl et al. {WO 2000/59506} - see, for instance, Example 83 on page 81;

b) Yasuda et al. {CA 105:210391, 1986} - see, for example, the compound of CA Registry No. 16408-45-0; or

c) Schneiders et al. {CA 77:68079, 1972} - see, for example, the compound of CA Registry No. 26261-14-3.

Each of the above cited prior art disclose at least one compound that is embraced by the instant claimed invention. Therefore, each of the cited prior art anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-17, 19, 20, 22, 24 and 26-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robl et al. {WO 2000/59506}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims imidazole compounds. Robl et al. (pages 2-6 and 25-39; and especially the Example 83 on page 81) teach imidazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating Type II diabetes).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, Type II diabetes. The

instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

January 22, 2007